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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,291	07/28/2003	Guangqiang Jiang	A329-USA	6474

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EXAMINER	
GEDEON, BRIAN T	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,291	JIANG ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. This action is in response to the amendment after non-final filed 2 June 2008.

2. The declaration under 37 CFR 1.132 filed 2 June 2008 is sufficient to overcome the rejection of claims 1-3, 5-7, 10-16, 19, 23, 25, and 26, as well as claims 20 and 21 based upon Chatterjee et al. (US Patent no. 5,677,072) in view of Whitehurst et al. (US Patent no. 6,735,475).

Response to Arguments

3. Applicant's arguments with respect to the pending claims have been considered but are moot in view of a new ground(s) of rejection. The new grounds of rejection are presented below.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3 and 5-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US Patent no. 5,688,731) in view of Tziviskos et al. (US Patent no. 6,011,993).

In regard to claims 1, 10, and 13, Chatterjee et al. disclose a method for producing a tetragonal zirconia polycrystal ceramic, col 3 lines 65-67, and can yield tetragonal zirconium oxide (ZrO_2), col 5 lines 23-24. The process for creating the material involves a sequence of sintering and compacting happening consecutively, though the order in which one occurs is not critical, col 5 lines 50-58, wherein the compacting step is hot isostatic pressing. The compaction and sintering process allows for a ceramic product that has a high density, at least greater than 90% of theoretical, col 5 lines 64-67. Though, Chatterjee et al. does teach that hot isostatic pressing can achieve a near 100% theoretical density and improve the fracture toughness, col 7 lines 51-54. The process of Chatterjee et al. can achieve a grain size from about 0.1 microns to 0.6 microns, with an average grain size of less than 0.3 microns, col 5 lines 5-6. Compaction (i.e., hot isostatic pressing) occurs at controlled pressures (i.e., from 69-207 MPa —100 MPa preferred), col 6 lines 8-25, in a controlled atmosphere or argon, col 7 lines 54-55, and at temperatures between 1300^0 to 1700^0 C, col 6 lines 36-38. The sintering process, in addition to the compaction process, can also aid in reducing porosity, col 6 lines 29-30. Chatterjee et al. teach that the tetragonal zirconia ceramic is known for its excellent electrical conductivity, high fracture toughness, and wear and abrasion resistance, col 3 lines 29-33. However Chatterjee et al. do not teach its use as an implantable medical device housing. Tziviskos et al. describe an implantable medical device 10 housing, wherein the hosuing 14 is made of a biocompatible ceramic material, for example zirconium oxide (ZrO_2) with about 3 mole percent yttrium, col 4 lines 32-37. Tziviskos et al. teach that ceramics are a preferable material for such

housings because ceramics have enhanced strength with high mechanical resistance to protect the electronics inside, as well as being transparent to interfering electromagnetic fields, col 1lines 14-15, 39-41 and col 2 lines 2-6. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the process of Chatterjee et al. to produce the implantable housing of Tziviskos et al. since Tziviskos et al. teach that implantable housing should have high mechanical resistance wherein a ceramic, such as a zirconium crystal alloy (ZrO_2) as created and taught by Chatterjee et al., would be an appropriate material.

In regard to claims 2, 3, 11, and 12, Chatterjee et al. uses 3 mole percent of Yttria to yield tetragonal zirconium oxide (ZrO_2), col 5 lines 23-24 and col 4 lines 9-42.

In regard to claims 6 and 15, the sintering process of Chatterjee et al. is controlled at a temperature between 1300^0 C to 1600^0 C, col 6 lines 36-37.

In regard to claims 7 and 16, the hot isostatic pressing process of Chatterjee et al. is controlled at a pressure between 69 and 207 MPa, preferable 100 MPa, col 6 lines 8-25.

In regard to claims 8, 9, 17 and 18, Chatterjee et al. teach that the hot isostatic pressing process occurs in argon, col 7 lines 54-55.

6. Claims 5, 14, 19-23, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US Patent no. 5,688,731) in view of Tziviskos et al. (US Patent no. 6,011,993), further in view of Whitehurst et al. (US Patent no. 6,735,475).

In regard to claims 5, 14, 19, and 23, Chatterjee et al. in view of Tziviskos et al. substantially describe the invention as claimed, except for the dimensions of the implantable housing. It should also be added that Tziviskos et al. includes two metallic feedthrough connectors 30, that supply electrodes with stimulation pulses, col 5 lines 30-37, and also includes a metallic band brazened to said housing to create a hermetic seal, col 2 lines 25-28 and col 4 line 63 - col 5 line 10. Whitehurst et al. describe an implantable microstimulator housing with dimensions of 3-5 mm or less in diameter, 20-35 mm or less in length, col 15 lines 50-53, wherein the microstimulator hosuing is a thin elongated cylinder, col 15 lines 56-59. The microstimulator may be inserted into a patient via a hypodermic syringe, col 15 lines 60-62. Whitehurst et al. also teach that microstimulator housings can be made from ceramic, just as Tziviskos et al., and Chatterjee et al. suggest that the product produced can be dimensioned and shaped in any predetermined form. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 100 mm or less for length, 10 mm or less for diameter, and 2 mm or less for wall thickness of the claimed tube since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984). It is also well known in the art that the dimensions of the

BION microstimulator, which is the embodiment of the Whitehurst et al., are of the millimeter scale or smaller.

In regard to claims 20 and 26, the hot isostatic pressing process of Chatterjee et al. is controlled at a pressure between 69 and 207 MPa, preferable 100 MPa, col 6 lines 8-25.

In regard to claims 21 and 25, the sintering process of Chatterjee et al. is controlled at a temperature between 1300^0 C to 1600^0 C, col 6 lines 36-37.

In regard to claims 22, 27, and 28, Chatterjee et al. teach that the hot isostatic pressing process occurs in argon, col 7 lines 54-55..

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (US Patent no. 5,688,731) in view of Tziviskos et al. (US Patent no. 6,011,993), further in view of Whitehurst et al. (US Patent no. 6,735,475) and Tsukuma et al. (US Patent no. 4,587,225).

Chatterjee et al. in view of Tziviskos et al. and Whitehurst et al. substantially describe the invention as claimed except bending stress of the implantable hosuing material. Tsukuma et al. is reference to provide the teaching that hot isostatic pressing processes for producing a tetragonal zirconia polycrystal ceramic is controlled at an atmosphere in argon, col 8 lines 61-66. The ceramic of Tsukuma et al. has a three point bending stress of at least 1700 MPa, col 3 lines 21-35. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process for making a ceramic tube described by Chatterjee et al. in view of Tziviskos et al. and Whitehurst et al. since it would involve applying a known technique

in the art to a known process to yield predictable results, namely improve the mechanical strength.

Conclusion

8. In view of the new grounds of rejection, this action is made **NON-FINAL**.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

Carl H. Layno
Examiner
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/B. T. G./
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